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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/660,812	09/12/2000	Kenny L. Dang	ACS 54573 (23111)	8165

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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 03/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/660,812

Applicant(s)

DANG ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 5, 11-13, 24 and 30-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-10, 14-23, 25-29 and 33-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 September 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,4-6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. This application contains claims directed to the following patentably distinct species of the claimed invention:

- 1) Figures 4-6 show the embodiment of the first species.
- 2) Figures 7-9 show the embodiment of the second species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, none of the claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of **all claims** readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Mr. John S. Nagy on 3/5/02 a provisional election was made without traverse to prosecute the invention of Species 1, claims 1-4, 6-10, 14-23, 25-29 and 33-40. Affirmation of this election must be made by applicant in replying to this Office action. Claims 5, 11-13, 24 and 30-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

2. The second reference listed on the 1449 of the IDS filed 12/13/01 as Paper No. 5 is incorrect, according to the copy of the reference submitted. Application number "2001/0021879" should be --2001/0021870--. A note has been made by the Examiner on the 1449 indicating the error and correction thereof.

Drawings

3. The drawings are objected to because of the following:

- ✓ a. In Figure 2, there are two "20" and one of the two is not directed to the tubular cover.
- ✓ b. In Figure 9, there are two "33" and one is not directed to the overlap portion.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

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✓ 4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "proximal end 32", mentioned on page 13, line 4, is not shown in Figures 7-9. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

↗ 5. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

→ 6. The disclosure is objected to because of the following informalities: it appears that page 12, lines 13-15 is incorrect, according to Figure 4, which shows opposite of what is stated. Figure 4 shows that the proximal end 26 of second section overlaps the distal end 22 of the first section 21.

Appropriate correction is required.

Claim Objections

7. Claims 14, 16, 18, 33, 35 and 37 are objected to because of the following informalities:

- ✓ a. Claims 14 and 33, the word --stent-- should be inserted before "proximal".
- ✓ b. Claims 16 and 35, "polyerethane" should be changed to --polyurethane--.
- ✓ c. Claims 18 and 37, change "forms" to --form--.
- ✓ d. Claim 33, change "stat" to --stent--.

Appropriate correction is required.

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Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-10, 14-19 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 1 is indefinite because as a product claim, applicant is only positively claiming an overlap portion and not the cover material and stent. The phrase "associated with" is unclear in providing a structural and functional nexus between the overlap portion and the cover material and stent. Therefore, all claims dependent on claim 1 that further limit the cover material and/or stent are indefinite because these elements are not being claimed in claim 1.

10. Claims 2-4, 6-10, 14-19 and 39 recite the limitation "the assembly" in line 1. There is insufficient antecedent basis for this limitation in the claim. Independent claim 1 is only claiming an overlap portion, not an assembly. It is unclear what structural elements constitute "the assembly".

11. Claims 9 and ^{cancelled}28 are indefinite because they are not commensurate with what is shown in the Figures, specifically Figure 4. It appears from Figure 4 that the proximal end of the *second* section forms the overlap portion with the distal end of the *first* section.

12. Claims 16 and 35 are indefinite for claiming subject matter not supported in the specification. PTFE is not mentioned in the specification for being a cover material option. It appears that PTFE should be PET.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

14. Claims 1-4, 6-8, 14-19 and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Sogard et al. (USPN 6,139,573 as cited in applicant's IDS).

Sogard et al. discloses a conformal laminate stent device with all the elements of claim 1. See Figures 6 and 7 for the cover material including inner tubular liner (14) and cover (19) together providing as the overlap portion on a stent (10).

Claims 2-4, see Figures 6 and 7 and column 4, lines 14-29 for cover material distal and proximal ends attached to the stent and the overlap portion being positioned between the two ends.

Claims 6-8, see Figure 6 for first section (19) and second section (14) both having proximal and distal ends and being shorter than the overall length of the stent (10).

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Claim 14, see column 12, lines 22-25 for cover material being attached to the distal and proximal ends of the stent.

Claim 15, see column 7, lines 56-59 for attachment by adhesive.

Claim 16, see column 8, lines 10-13 for cover material being of ePTFE.

Claim 17 and 18, see Figure 21 for more than two sections forming more than one overlap portion.

Claim 19, see column 11, lines 1-4 for cover material being within required thickness range.

Claim 39, because cover material is made of ePTFE, it is inherently a porous material.

15. Claims 1-4, 6-10, 14, 17-23, 25-29, 33, 36-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Freidberg (USPN 6,254,627).

Freidberg discloses a jacketed stent assembly comprising an expandable stent jacketed with a cylinder of biocompatible, non-thrombogenic expandable material with all the elements of claims 1 and 20. See Figure 7 and columns 5-6, lines 63-6 for an intravascular stent (12) having proximal and distal ends, a tubular cover material (14) covering at least a portion of the stent, and an overlap portion formed by the cover material that shortens when the stent expands.

Claims 2-4 and 21-23, see Figure 7 and column 4, lines 5-8 for cover material distal and proximal ends being attached to the stent and the overlap portion being positioned there between.

Claims 6-10 and 25-29, see Figure 7. The first three complete wraps is the first section and the next 2+ wraps is the second section, both having proximal and distal ends and both being shorter than the overall length of the stent. The first section and second section overlap and are

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configured for sliding movement at the overlap portion when the stent is expanded (column 6, lines 1-6).

Claims 14 and 33, see column 4, lines 5-7 and columns 5-6, lines 63-6.

Claims 17-18 and 36-37, see Figure 7. The first two complete wraps is the first section, the next two complete wraps is the second section, and the next 1+ wrap is the third section. Between the sections is an overlap section, so that there is more than one overlap portion along the stent.

Claims 19 and 38, see column 4, lines 32-36 for cover material being within specified thickness range.

Claims 39 and 40, see column 4, lines 14-27.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 15 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freidberg.

Freidberg discloses a jacketed stent assembly comprising an expandable stent jacketed with a cylinder of biocompatible, non-thrombogenic expandable material with all the elements of claims 1 and 20, but is silent to the additional limitation of the cover material being attached to the stent by an adhesive, as required by claims 15 and 34. Freidberg discloses that the cover

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material (jacket) may be secured to the stent by any suitable means (column 4, lines 5-6) and securing the sides of the stent cover together is done by mechanical means that are old and well known in the art, including adhesive bonding (column 5, lines 35-37). Therefore, it would have been obvious to one of ordinary skill in the art to use adhesive bonding to attach the cover material to the stent by an adhesive.

18. Claims 16 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freidberg in view of Sogard et al.

Freidberg discloses a jacketed stent assembly comprising an expandable stent jacketed with a cylinder of biocompatible, non-thrombogenic expandable material with all the elements of claims 1 and 20, but is silent to the cover material being made from ePTFE, what Examiner interprets as PET or polyurethane, as required by claims 16 and 35. Sogard et al. discloses a conformal laminate stent device with a cover material made of ePTFE in order to provide a surface that is inherently resistant to adhesive bonding, which imparts a natural anti-thrombogenic characteristic to the surface to the cover material. It would have been obvious to one of ordinary skill in the art to make the biocompatible, non-thrombogenic expandable material of Freidberg of ePTFE in order to provide a surface that is inherently resistant to adhesive bonding, which imparts a natural anti-thrombogenic characteristic to the surface to the cover material. See column 2, lines 40-45.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with first Fridays off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 305-3590. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.

Urmi Chattopadhyay

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David J. Isabella
Primary Examiner

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March 8, 2002